K 073010

SECTION 4 → 510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR¶807.92(a).

807.92(a)(1)

Submitter Information

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Date: Oktober 16, 2007

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FDA CDRH DMC

OCT 2 5 2007

Received

807.92(a)(2)

Trade Name: Royale AE 9036 LSP

Common Name: Injector

Classification Name(s): Intraocular lens guide,

Classification Number: CFR 886.4300

807.92(a)(3)

Predicate Device(s)

510(k) Number	Device
K 023737	Injector Royale® AE 9045
K 003768	MONARCH® II IOL Delivery System
K 011392	Micra Instument Ltd. Lens Insertion System

807.92 (a)(4)

Device Description

The injectors are autoclavable, reusable titanium hand pieces which are used to deliver folded intraocular lenses into the eye for replacement of the human crystalline lens. They are a modification to the previously cleared Injector Royale AE 9045 K023737. The injector reusable hand piece accepts the cartridges with a sterile single use cartridge which incorporates the folded lens and delivers the lens by using a plunger to express

the lens. The plunger's head is contoured to provide a good contact to the lens as well as an adequate clearance for the trailing haptic. The plunger is advanced by direct forward motion applied to the syringe type plunger. Due to the ball bearing technology a smooth and well controlled lens delivery is ensured

807.92(a)(5)

Intended Use(s)

The Royale® 9036LSP Injectors are reusable instruments to assist in implanting Alcon ACRYSOF® foldable intraocular lenses during a normal small incision cataract surgery. They are designed to incorporate Monarch III cartridges Type D and Monarch II type C cartridge for foldable intraocular lenses

807.92(a)(6)

Technological Characteristics

The plunger's head is contoured to provide a good contact to the lens as well as an adequate clearance for the trailing haptic. The plunger is advanced by direct forward motion applied to the syringe type plunger. Due to the ball bearing technology a smooth and well controlled lens delivery is ensured. This product has a plunger style mechanises which is similar to the predicate device AE-9045 and the Micra Instument Ltd. Lens Insertion System and is different from that of the Monarch II IOL delivery system as this is a screw type mechanism. Some of the dimensions of the AE-9036LSP and that of the AE-9045 are the same. The Overall body diameter is 10 mm and the length is 99.60mm for both the injectors. The Thumb ring diameter is 28mm for both of the injectors. Both the AE-9045 and the AE-9045LSP have similar plunger style mechanism and the plungers are similar except for dimensional difference in the tips. Both the AE-9045 and the AE-9036LSP the injectors are made of Titanium Grade 5 (ASTM 136) and/or medical grade stainless steel (DIN ISO 5832-1).

Tests Performed

The objective of the study was to demonstrate that the IOLs remain mechanically and optically undamaged after manipulation with the AE-9036LSP injector in combination with one-piece ACRYSOF® acrylic foldable IOLs (SN60WF) for posterior chamber application and Alcon III Monarch Cartridges as manufactured by ALCON Laboratories Inc. This test report is in Tab E. The instrument has passed all the necessary tests and has been qualified for the DFU.

In Tab F, G and H we have performed various cleaning test to validate our Direction for use document which will be supplied with injector. In Tab F we have performed the

Acrinol test where we have evaluated the cleanliness by Acrinol staining and light microscopy methods. In Tab G we have done the Bio-Burden test to evaluate cleanliness by microbiological methods and light microscopy. In Tab H we have performed the Intra-ocular irritation test. The instrument has passed all three tests successfully.

In conclusion we have performed all the tests that were required to qualify the lens accordance with the provisions of ISO 11979-2 in regards to their optical properties, ISO 11979-3 [2] in regard to their mechanical properties, and the FDA IOL Guidance Document. We have perfomed more extensive cleaning tests then what we have done for our predicate device AE-9045. We have perofrmed the Acrinol test, the Bioburden test and the Intrsaoccular irritation test. Ths instrument has passed all the tests succsefully.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Asico LLC
c/o Ms. Silvia Ankova
Underwriters Laboratories, Inc.
333 Pfingsten Rd.
Northbrook, IL 60062

NOV 07 2007

Re: K073010
Trade/Device Name: Royale AE 9036 LSP
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular Lens Guide
Regulatory Class: Class I
Product Code: MSS
Dated: November 1, 2007
Received: November 2, 2007

Dear Ms. Ankova:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M. B. Eydelman, MD

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 3 → Indications for Use Statement

510(k) Number (if known): K073010

Device Name: Injector Royale® AE-9036 LSP

Indications for Use:

The Royale® AE-9036 LSP Injectors are reusable instruments to assist in implanting Alcon ACRYSOF® foldable intraocular lenses during a normal small incision cataract surgery. They are designed to incorporate Monarch III cartridges D and Monarch II cartridge C for foldable intraocular lenses. The cartridges are loaded into the injector body. By pushing the piston, the lens will be removed out of the cartridge and delivered to the desired position.

Prescription Use ____X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ph.D.

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K073010